

The APHL/CDC Partnership: Strengthening Public Health Laboratories

**REPORT ON 2015-2016** 



#### **About APHL**

The Association of Public Health Laboratories (APHL) works to strengthen laboratories serving the public's health in the United States and globally. A national nonprofit, the organization represents state and local governmental health laboratories in the US. These members, known as public health laboratories, monitor and detect health threats to protect health and safety.

Founded over 60 years ago as a forum for state public health laboratory directors, APHL has expanded to encompass laboratories and staff from multiple disciplines, including environmental, agricultural and food safety laboratories. APHL collaborates with laboratory and public health partners to assure effective surveillance, detection and response to health threats. During public health emergencies, APHL operates as a coordinating center for laboratory response. With experience in 31 countries on five continents, APHL is recognized internationally as a leader in laboratory science and practice.

The first cooperative agreement between the US Centers for Disease Control (CDC) and APHL began in 1989. The relationship has broadened ever since and now encompasses the range of public health.



**COVER:** Rabies lab scientist Keisha Friday of the Maryland Public Health Laboratory prepares necropsy processing for postmortem diagnosis of rabies in animals. This method uses the Direct Fluorescent Antibody test.

ABOVE: Analyst Tom Tarantelli of the New York State
Department of Agriculture & Markets Food Laboratory draws
a sample color extract with a syringe, which will be inserted
into the AIS Multi-Spotter.

BACK COVER: Justin Grynovicki of the Maryland Public Health Laboratory Molecular Diagnostics Unit analyzes real-time RT-PCR Zika virus data from the 7500 Fast DX PCR instrument. "This year, APHL's expertise and support were critical for meeting urgent needs such as the Zika response, ongoing needs such as workforce development and initiatives that broke new ground in infectious disease, advanced molecular detection and antibiotic resistance. This success builds on a long relationship with CDC that has elevated the quality of public health laboratory systems here and abroad. APHL will continue to be an essential and valued partner."

#### MICHAEL F. IADEMARCO, MD, MPH

Captain, US Public Health Service
Director, Center for Surveillance, Epidemiology, and Laboratory Services
Office of Public Health Scientific Services
US Centers for Disease Control and Prevention
Department of Health and Human Services



"CSTE and APHL are indispensable partners—neither can be successful without the other being successful. We appreciate APHL's leadership in informatics, its generosity in sharing best practices in NGO internal management and its collaboration on joint policy initiatives. Both organizations work side-by-side along with our member jurisdictions on state-of-the-art approaches to modernizing surveillance."

#### **JEFFREY ENGEL, MD**

Executive Director, Council of State and Territorial Epidemiologists

# **Making the Connection to Health**

system is only as strong as its connections. APHL highlights these connections and functions as a nexus. bringing science, policy and practice together to support and empower greater excellence in the overall public health system.

Our connections are critical: To respond to crises such as Zika, we use the links forged in multiple, diverse areas—FDA policy, social media communication, training programs—to act faster and more effectively than state public health laboratories can on their own.

Our connections are flexible: For instance, the impact of the APHL Informatics Messaging Services (AIMS) platform goes far beyond its uses for the public health laboratory system—it has become the gateway to public health data for users throughout the health system. AIMS' power made it the natural choice when CDC's Advanced Molecular Detection (AMD) program sought a new, faster process for influenza data transfer.

We connect to the future. Using the cooperative agreement, we cultivate new and innovative ways to support the people and skills needed in the public health laboratory system. One way is by developing a new APHL/CDC fellowship program based on core competencies and building in a core curriculum, with the first group of fellows tackling issues around antibiotic resistance.

And we connect through sharing information and stories, such as in this report. You'll read about resourceful ways that APHL and our public health laboratory members shape national and global health outcomes by continuously improving systems and practices. I'm proud of my connection to them.

Scott J. Becker

Scott Becker, MS EXECUTIVE DIRECTOR, APHL

# **Executive Summary**

# **IMPACT BY PROGRAM**

<u> </u>	INFECTIOUS DISEASE	<ul> <li>Combating Zika</li> <li>Fighting Antibiotic Resistance</li> <li>Expanding AMD's Benefits</li> <li>Building European Capacity</li> </ul>
	INFORMATICS	<ul><li>Expanding Technical Assistance</li><li>Multiplying AIMS' Effect</li></ul>
Hypupill C.C.J.J.	WORKFORCE	<ul> <li>Growing Tomorrow's Leaders</li> <li>Encouraging Students' Enthusiasm</li> <li>Creating Long-lasting Impact</li> </ul>
[8-8-9]	PREPAREDNESS	<ul> <li>Responding to Zika and Ebola</li> <li>Studying Laboratory Safety</li> <li>Convening Responder Communities</li> </ul>
	GLOBAL HEALTH SECURITY AGENDA	<ul><li>Training for Biosafety and Biosecurity</li><li>Transforming Uganda's Laboratory</li></ul>
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	QUALITY SYSTEMS	<ul> <li>Launching National Database</li> <li>Answering Vital Questions</li> <li>Leadership in Newborn Screening</li> <li>Guiding System Excellence</li> </ul>
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## AMD PROJECT WINS CDC AWARD

#### **Building a Better Vaccine**

The three National Influenza Reference Centers (NIRCs) are critical to US response and serve as the authorities on virus culturing even as many state public health laboratories have lost that capability. CDC wanted to take the next step: performing whole genome sequencing before culturing to improve the timeliness of influenza data. A pilot project at the Wisconsin State Laboratory of Hygiene (one of the NIRCs) proved the value of this concept. One result: the participants in this APHL/CDC Whole Genome Sequencing Data Exchange project won the Excellence in Domestic Partnering award from CDC's National Center for Immunization and Respiratory Diseases.

#### **Advantages of "Sequence First"**

Changing from a "culture first" approach to "sequence first" would enable CDC to receive data two weeks sooner on the virulence, drug resistance and ease of transmission of each strain that's in circulation—details that help determine which subset of viruses to culture. If public health laboratories wind up using sequencing for this purpose, it could allow CDC to send information faster to the World Health Organization and speed up each year's vaccine development process by months.

"By changing the paradigm, the NIRC could collaborate with CDC experts in real time. APHL staff made it happen we simply couldn't do it without them."

**DANIEL JERNIGAN, MD, MPH** 

Director, Influenza Division

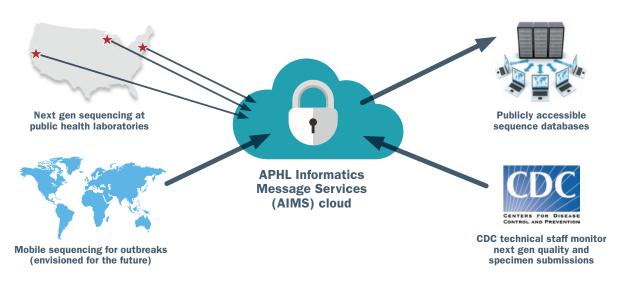
National Center for Immunization and Respiratory Diseases, CDC



Yet the project faced a bottleneck when sending the vast amount of data required for each sequence. The elegant solution to creating a faster pipeline was to copy the CDC's bioinformatics infrastructure onto the APHL Informatics Messaging Services (AIMS) platform. AIMS and its associated tools cut the uploading time for a sequence from 24-48 hours to under seven hours, and cut the transmission time from eight hours to one. Also, this speedier, simpler process didn't require costly technology upgrades at the state level.

The other two NIRCs (New York and California) will now join this collaboration with CDC's Advanced Molecular Detection Program, APHL's Informatics and Infectious Disease teams, the Wisconsin laboratory and two companies, CLC bio and Clarity LIMS systems. The remaining two years of this three-year project hold great promise for innovation, analytics and data availability.

# **Cloud Sequencing to Support Influenza Surveillance**



# **INFECTIOUS DISEASE**



#### **Incident Command Structure** Formed to Combat Zika

Emerging infectious diseases are part of our team's portfolio—we respond to emergencies regardless of funding. Initial concerns about Zika surfaced in late 2015 and within two months APHL instituted an incident command structure with 16 people assisting with response as the crisis escalated.

Starting with a meeting every Monday, our staff act as conveners and problem-solvers:

- Continuously monitoring the situation and developing guidance to reflect the latest data
- Serving as a liaison between public health laboratories and external partners such as manufacturers and diagnostic services firms
- Participating in two weekly CDC calls
- Sending communications to public health laboratories up to three times a week
- Discussing new Emergency Use Authorizations with FDA

Selected APHL staff have devoted 40 percent of their time since January 2016 to helping public health laboratories tackle Zika. Unlike other illnesses, the demand for testing is constant, and with US transmissions appearing, their efforts will accelerate.

Laboratorian Helen Chan of the Massachusetts State Public Health Laboratory works on arbovirus response activities in viral serology.





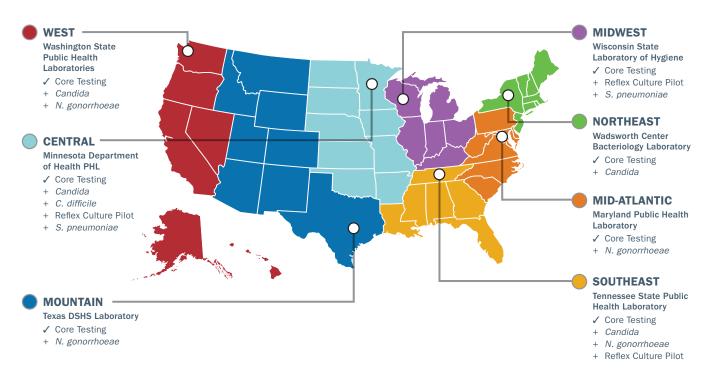
Laboratorian Pinal Patel of the Massachusetts State Public Health Laboratory works on arbovirus response activities in molecular diagnostics.

#### **Collaborating Against Antibiotic Resistance**

APHL and CDC had strategized for years on how to tackle antibiotic resistance. In December 2015, Congress responded to urgent calls for action with \$160 million in funding for the CDC's Antibiotic Resistance (AR) Laboratory Network. Because of the advance thinking, we could rapidly put a plan into action: APHL helped CDC establish the criteria for choosing the seven regional labs that will help track changes in resistance and identify outbreaks with local technical support.

This network is part of the CDC's Antibiotic Resistance Solutions Initiative and will support comprehensive and coordinated public health action against AR across states, counties and cities. Capacity-building moves include adding cutting-edge technology at the local level: All public health laboratories will develop whole genome sequencing capabilities so they can perform confirmatory testing of carbapenem-resistant Enterobacteriaceae (CRE), a family of superbugs whose spread jeopardizes modern medical advances.

# CDC Antibiotic Resistance Laboratory Network: 7 Regional Labs



# **Expanding AMD's Benefits**

Advanced molecular detection (AMD) technology is an enormous opportunity for public health. By providing more detailed and precise data, AMD makes it easier to detect and address agents of disease. APHL plays a key role in disseminating AMD technology. In addition to collaborating on the award-winning influenza AMD project (see page 3), APHL aids staff training and facilitates connections to reference centers. These capacity building efforts address local surveillance of tuberculosis, hepatitis C and unexplained respiratory disease outbreaks.

Every year, the APHL/CDC Bioinformatics Fellowship trains bioinformaticians to apply their skills to public health. In past years, all fellows were placed at CDC. This year one of the six new fellows will train at Minnesota's public health laboratory—a testimony to state labs' growing expertise.

#### **Building Capacity in Europe**

To counter a constant global threat, most countries seek to establish their own National Influenza Center. But this entails a steep learning curve. Through APHL's new Quality Assurance Mentorship, public health laboratories are confidently progressing on this path in five countries: Albania, Montenegro, Macedonia, Kosovo and Bosnia and Herzegovina. The APHL team has built strong relationships with dedicated staff as they transform their European labs into internationally recognized facilities.



Rolinda Eddings MT(ASCP), clinical laboratory scientist at the Tennessee Department of Health, Division of Laboratory Services, analyzes data to determine Mycobacteria genus and species using the MALDI-TOF (Matrix Assisted Laser Desorption Ionization-Time of Flight) Instrument. This cutting-edge technology is used to identify bacteria, fungi and mycobacteria.

# **INFORMATICS**



#### **High ROI for Technical Assistance to States**

As APHL's informatics team grew from six full-time staff to 11, its technical assistance (TA) team grew from one to five full-time equivalents, forming a deep "bench" that's instantly available to state public health laboratories to bridge gaps in expertise. TA team members deploy with a focused, accelerated approach and give states a broad base of resources. If the TA staff doesn't have the answers internally, it acts as a conduit to a wider network of subject matter experts who take on state challenges: requests for service, technical architecture support, project coordination and help with readiness for meaningful use and other national standards.

TA staff not only provide technical expertise, they also transfer knowledge, grow informatics capacity and foster critical collaboration between local entities. With a concentrated

effort to finish the work, this model specifically the onsite visit—has proven effective in bringing projects on board.

#### **Building on Success**

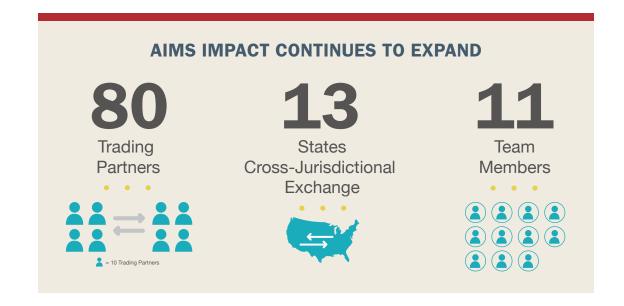
This team effort magnifies the powerful impact of previous TA work: 47 state laboratories received technical assistance from APHL's Public Health Informatics Project to successfully implement a messaging platform from concept to completion.

The project facilitates the goal of nationwide electronic laboratory data exchange by supporting collaborations that strengthen the public health laboratory community. For instance, it enables timely, detailed electronic influenza reporting that boosts situational awareness and strengthens the nation's preparedness for an emergency.

"Virtual assistance has been wonderful, but that first site visit was critical to us because the architecture [of the pilot program] was so complex. Having APHL's expertise helped us immensely."

**SARAH SOLARZ** 

Minnesota State Department of Health



417,270 **AIMS MESSAGE VOLUME IN 2015** 2,747,368 **AIMS MESSAGE VOLUME IN 2016** (FIRST 8 MONTHS) 3,801,483 **ALL-TIME TOTAL** These numbers will continue to trend up exponentially

once our latest projects move into full production.

#### The Power of the Cloud

APHL began its Informatics program a decade ago with a project to deliver standardized electronic influenza laboratory surveillance data to CDC. Today, the secure APHL Informatics Messaging Services (AIMS) cloud computing platform supports applications with software and infrastructure as a service. By helping clients analyze, visualize and report data, AIMS saves them time and money.

AIMS is the leading choice for data transmission among public health laboratories and agencies and is an increasingly valuable entry point to public health for other users.

# A NATIONAL RESOURCE FOR INTEROPERABILITY



# WORKFORCE



#### **Growing Tomorrow's Leaders**

APHL's Emerging Leaders Program (ELP) is a success that is elevating both the laboratorians who graduate from the program and their labs. These leaders, by modeling best practices and encouraging their peers to follow suit, are making their environments more productive.

Eager to continue their progress, graduates of ELP created a community of practice. The Network of Laboratory Leadership Alumni (NOLLA) continues to evolve in its ninth year: It now includes a dyad program where an alumnus becomes the coach and strategic thinking partner for a new ELP coachee.

NOLLA has 25 coaches, 15 of whom are connected with Uganda as part of a new initiative. They'll be peer coaches for a cadre of high-potential, mid-level scientist-managers in a collaboration with the Uganda Ministry of Health and CDC Uganda. The participants' projects will improve the country's External Quality Assurance Program, implement and evaluate internal quality control procedures and develop recommendations for the national laboratory referral system. (For more details on APHL's work in Uganda, see p. 12.)

#### **ALUMNI FROM COHORT 7 SAID:**

"My participation has helped me grow not only as a leader in my own organization but also in my family and community."

"It was a challenging, rewarding, once-ina-lifetime experience. This program will have a positive effect on my growth as a leader throughout my career. I am grateful to participate in NOLLA and continue my connection with these amazing people."

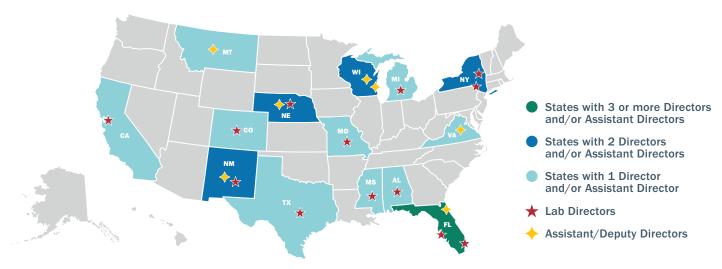


#### **Driving Student Excitement**

Designed by members of ELP Cohorts 6 and 7, ThatsSick.org is a virtual open house that introduces students to the excitement of public health careers. The designers worked with educators to create this dynamic, easy-to-use online resource.

#### THE PIPELINE EFFECT

Lab Directors and Assistant Directors Who Are ELP Alumni



# **National Laboratory Training Network**





COURSES (IN PERSON AND ONLINE)



REPRESENTED AT **HANDS-ON WORKSHOPS** 

- 99% of participants rated the course quality as "good" to "excellent"
- Packaging & Shipping Workshop attendees had an average knowledge gain of 30% (higher than the average pre-test scores)

#### **Long-lasting Impact**

"The ripple effect of APHL's investment two years ago in our Lean certification continues to this day, enriching our work and strengthening our contributions to this community and to our partners across the state and country.

Since our lab's implementation of Lean, our county's Public Health Department has repeatedly held us up as a model for other programs to emulate. The department also demonstrated confidence in the lab as a good investment by fully restoring the funding that was cut several years ago and approving the addition of another full-time microbiologist.

I continue to share the Lean knowledge I gained: I have contributed to a four-part APHL webinar series, an APHL quality improvement forum call, Lab Matters articles, an industry white paper, and during APHL annual meetings in a panel presentation, roundtable session, and pre-conference workshop. Our work with Lean also continues to harmonize with quality improvement efforts as we work towards accreditation."

#### Denise Lopez, MS, PHM

PUBLIC HEALTH LAB MANAGER, ELAP LAB DIRECTOR TULARE COUNTY PUBLIC HEALTH LAB, CALIFORNIA

#### Students Become Lab Jedi

"The Force" behind public health was revealed in a Star Wars-themed science day for middle school children and their parents, sponsored by APHL and the New Mexico Dept. of Health Scientific Laboratory. Some parents drove two hours to encourage their children's enthusiasm for science. Children extracted their own DNA and performed other lab activities while other kids watched the live stream of the event.

**INSET:** Darth Vader agar plate art

RIGHT: New Mexico microbiologists Mary Martinez, (left) and Windy Arellano, (far right), help a student examine microscopic specimens.



# **PREPAREDNESS**



#### Safety When Threats Converge

It wasn't a perfect storm, but it was close. The overlapping threats of Ebola and Zika posed significant challenges to preparedness in state and local public health laboratories.

But groundwork laid in the past five years meant these laboratories were well positioned to respond. APHL helped them deal with the differences in testing methods and the moving target posed by Zika. The APHL staff was a source for up-to-the-minute information and assisted members in obtaining training and instrumentation for testing. APHL also created risk assessment templates and guidance for bringing on new Zika assays.

To manage the threats, APHL coordinated vital agreements among labs to ensure redundancy and backup capacity. By June 2016, US public health laboratories could provide Zika virus laboratory testing coverage for all 50 states, using IgM ELISA, RT-PCR and PRNT assays.

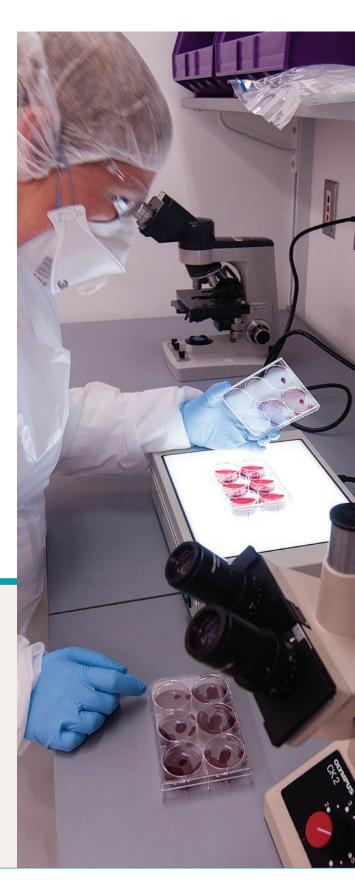
Simultaneously, APHL consulted with CDC subject matter experts, developed a pre-Ebola assay and advocated for wider distribution of Ebola assays, a position that was embraced as the number of states performing Ebola assays jumped from 11 to 45.

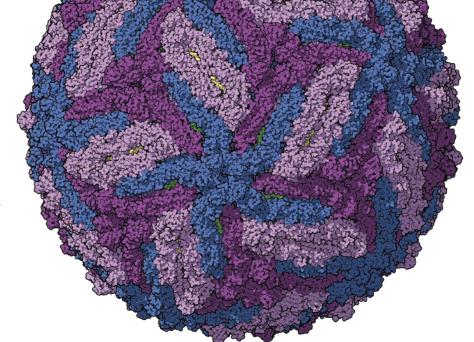
Virology and immunology scientist Sarah Langtry of the Maryland Public Health Laboratory prepares a reagent for a Zika Virus Plaque Reduction Neutralization Test (PRNT) in the BSL-3 training laboratory.

#### Why Conventional Methods?

A test that has fallen out of use—because another type of test is less expensive or newer—can turn out to be the best method when it comes to an emerging threat.

That's what we discovered with Zika: ELISA testing could be useful for certain asymptomatic pregnant women, for example, but many labs had stopped or limited this type of test and found it difficult to ramp up again. Testing guidance is complex and evolving. APHL's priority is that labs have what they need to make good strategic decisions.





#### **Conducting a Safety Study**

For all their great benefits, new tests and technologies can carry dangers to laboratory staff. Concerns after incidents involving safety and accuracy led APHL's Sentinel Laboratory Partnerships and Outreach Subcommittee to conduct a safety study in five public health laboratories.

The study results were included in American Society for Microbiology guidelines and in communication to the College of American Pathologists. APHL is developing further outreach and public-private alliances to help protect laboratorians.

"It's an excellent example of the **Laboratory Response Network** in action. This partnership allows us to quickly release important information to the clinical laboratories to minimize laboratory worker illness while maintaining high quality laboratory testing."

**CHRISTINA EGAN, PhD** 

Chief, Biodefense Laboratory Wadsworth Center, New York State Department of Health

# **Convening Responder Communities**

APHL convened a conference on the national Laboratory Response Network in September 2015 with more than 350 attendees, an event that cemented existing partnerships and helped develop new ones. APHL offered a pair of training courses on conventional lab methods as well as assistance to clinical labs on keeping this essential knowledge alive.

Our buy-in from labs is such that our annual All-Hazards Survey had a 100 percent return rate. The results show that while labs are resilient, they still lack technology, equipment and workforce resources.

Zika virus capsid, colored per chains.



## **Biosafety and Biosecurity** Committee

Building on its longtime involvement in the field.

APHL established a Biosafety and Biosecurity Committee to provide leadership on policies and practices, and created a listserv for a Community of Practice for Biosafety Officers.

Alexander Kim of the Maryland Public Health Laboratory's Molecular Diagnostics Unit/Biosafety Level 3 laboratory, as he trains to handle Ebola specimens wearing personal protective equipment for BSL-3 plus infectious agent PCR testing.



# **GLOBAL HEALTH SECURITY AGENDA**



Alpha Diallo, MD (left) introducing objectives of the Biobanking, Biosafety and Biosecurity Workshop in Conakry, Guinea (March 2016). At the head table: Guinea Ministry of Health leadership, WHO representative and workshop faculty.



### **Biosafety and Biosecurity** Training and Certification

APHL opened a permanent field office in Guinea to help create a strong national public health laboratory system at all levels. This comprehensive effort involved a range of tactics from helping to update the National Strategic Plan to protecting laboratory workers and the public from pathogens.

For the latter, APHL leveraged its long history of laboratory safety training: first with a workshop on Biobanking, Biosafety and Biosecurity, then by building local capacity to certify and safely use biosafety cabinets. These steps protect laboratory workers from exposure to pathogens and create a sustainable pipeline of engineers to support biosafety efforts.

By partnering with the nonprofit Eagleson Institute (which has trained 15 biosafety engineers including ones in Kenya), APHL is using a proven model: bring in a veteran engineer to mentor and assess local engineers, who then train future engineers. Since there's a dire need for these certified experts in Africa, the training will aid APHL's ongoing work in Guinea and Sierra Leone, then expand across the continent and eventually into Asia.

#### Transformation in Uganda

When Uganda decided to convert its public health laboratory into a national reference laboratory, it faced a major hurdle. No one at the lab had seen this done before. To solve the dilemma, APHL's Global Health program proposed a "twinning" arrangement with the New Mexico public health laboratory because it underwent a similar makeover when it moved from an old, cramped building to a state-of-the-art facility on a campus.

Twinning involves extensive training, with a US lab sending its staff overseas and then welcoming the other lab's staff. With this approach, New Mexico laboratorians transferred their knowledge as the Ugandans, led by director Steven Aisu, asked questions about lab operations.

The New Mexico team had previously done a twinning project with Paraguay via APHL and eagerly offered technical assistance, management and leadership training, and advice on how to work with agricultural partners and other types of labs. Aisu explained that in the US, this collaboration may feel like working across silos, but in Uganda, it must bridge chasms.

APHL staff Kajari Shah, Chris Mangal and Ava Onalaja visit the new national public health laboratory in Kampala, Uganda.







The ELP cohort learns about Team Management Systems and their work profiles.

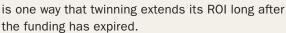
#### **Workforce Training**

In April, the Ugandan team boosted its professional development as part of APHL's Emerging Leader Program (ELP). Fifteen ELP alumni serve as mentors (one on site and others via Skype) for a set of interlocking projects aligned with GHSA, Ministry of Health and CDC priorities. (For more details, see page 8.)

In 2017, the Uganda laboratory will host a long-sought pilot fellowship with the goal of building a robust, holistic program that feeds staff directly into the national reference laboratory. It's also intended to connect laboratory workers to epidemiology staff. The next step: linking the fellowship to the CDC's Field Epidemiology Training Program so the entire range of participants can attend courses together.

#### **Ongoing Relationship**

David Mills, PhD, the former director of the New Mexico public health laboratory, retired in 2015 but made such deep connections that he continues to work with the Ugandan team ("my friends") and advise on further twinning efforts. This



"APHL's drive to increase access to CD4 and viral load testing for HIV in hard-to-reach areas has fascinated and humbled me. We are making

**BALBINA MADIMUTSA** 

Laboratory Mentor, Mashonaland West Province, Zimbabwe

the mountains. The women's appreciation is great."

an impact on young women who survive on gold panning and fishing in





#### **Zika Threat Inspires Unprecedented Effort**

In 2016, Zika dominated not only the policy arena but all of public health. Every capacity and capability was engaged in the response, alongside a protracted campaign to spur awareness in the public and Congress.

As a key player, APHL led expansions into new partnerships while collaborating to address the Zika menace. While we activated techniques, channels and partnerships honed through years of public policy work, the Zika campaign called for extraordinary efforts above and beyond anything APHL has ever done—including the effort to address Ebola response.

APHL had more than 70 meetings or events specific to Zika in the first six months of 2016. We participated in two to three weekly calls—two organized by the CDC and one by the White House. Multiple meetings at the White House focused on how to coordinate efforts, including updates to current responses, identifying problem areas and developing new strategies.

It was an amount of time and effort equivalent to a decade of public policy work—compressed into half a year.

#### **Education and Delays**

Our nation's biosafety capacities were measured and tested by the Ebola crisis. With that knowledge in hand, APHL explained to Congress how state and local public health laboratories were addressing Zika.

Yet federal decision-makers struggled to grasp the problem. Zika compounded the communication issues because of the disease's complex testing, which requires multiple steps and confirmations.

When Congress approved funding in September, the news was welcome but the months of delay meant that states were scrambling to tackle the virus instead of taking the latest steps in a long-term plan. "Despite the work of APHL and other partners, key House and Senate offices turned a deaf ear to the Zika response approach recommended by experts from CDC and NIH," wrote Peter Kyriacopoulos, APHL's senior director of public policy.

It is a familiar challenge for public health: how to create a compelling metric for a disaster that has yet to happen. As APHL shifts priorities this coming year, it will seek out the most effective approaches to educating Congress.

#### **More Partners, Deeper Relationships**

The Government Accountability Office, tasked with examining the funding directed to fight Zika, tapped APHL's expertise in framing the investigation. APHL was the first choice because it could offer the broadest perspective on the challenge.

Knowing that an outbreak or crisis can interrupt routine laboratory functions, APHL expanded involvement with the Centers of Medicare and Medicaid Services (CMS). This agency administers the federal Clinical Lab Improvement Act (CLIA) and inspects public health laboratories. To protect both APHL members and the public, it's important to talk with CMS/CLIA before an emergency happens.

APHL's policy experts also strengthened their dialogue with FDA, making strides toward vital emergency use authorizations for test kits.

And on Capitol Hill, APHL forged new contacts with the House Speaker's Office, House leadership offices and offices from the high-risk Gulf of Mexico states. By developing a new rapport and a broadened reach, APHL has put an important public health message in front of a bigger audience.

APHL reached in the other direction as well, letting members know about visits to Congressional offices for their states and territories. Members report on their testing programs, provide data that increases the knowledge on Capitol Hill and urge representatives to visit the labs to better understand their challenges. These relationships pave the way for more consistent and well-directed funding.



LEFT: From left to right: Jane Bigham of the Senate Health, Education, Labor and Pensions Committee (HELP), FDA Fellow Aravind Sreenath, Senate HELP Health Policy Advisor Julia Tierney and APHL Senior Director of Public Policy Peter Kyriacopoulos discuss the PHEP cooperative agreement. RIGHT: From left to right: Stephen Steigleder of the House Appropriations Committee (Minority Staff), Rhode Island State Health Laboratory Director Ewa King, PhD and Peter Kyriacopoulos discuss the need for a national biomonitoring system.





# **QUALITY SYSTEMS**



#### **Launching a National Database**

Lab directors lack a national test database that shows who has the knowledge and equipment to perform which tests. During an outbreak, it's critical to quickly locate labs with specific testing capabilities and where to turn for emergency reagent supplies.

After working on this issue for several years, APHL had a soft launch of the Public Health Laboratory System Database in the summer of 2016. It will blossom into a full launch and national test directory in the coming year. The service will be useful beyond emergencies, streamlining the process of generating reports to CDC and other agencies.



The Newborn Screening and Genetics Program and partners at the Colorado School of Public Health celebrate Newborn Screening Awareness month in September.

#### **Answering Vital Questions**

Quality systems are the backbones of public health laboratories, and like spines, they have to be as flexible as they are strong.

Through APHL's regular online Quality Improvement Forums and conference calls, members get immediate feedback across many levels and disciplines. Some issues, however, needed additional attention, such as the cascade of questions about the Individualized Quality Control Plan (IQCP) option under the Clinical Lab Improvement Act.

The IQCP offers new flexibility when ensuring quality test results. But members asked: What are the advantages? How do you make an informed decision? APHL was ready with answers and individual lab members went on to develop three presentations on the topic for APHL's annual meeting.

# Leadership in **Newborn Screening**

In its role as a convener for the field of newborn screening, APHL brought together 500 members of the community for the APHL Newborn Screening and Genetic Testing Symposium. The meeting addressed state, national and international newborn screening, genetic testing and policy issues.

APHL also developed and disseminated a best practices document and training webinar on inherited disorders. This guidance on screening, diagnosis and follow-up for hemoglobinopathies is valuable for state health laboratories, universities and community centers.

# **Guiding the Way to System Excellence**

APHL's Laboratory System Improvement Program (L-SIP) helps state and local public health laboratory systems become more effective through a guided process of performance evaluation, system improvements, and periodic evaluation and reassessment.

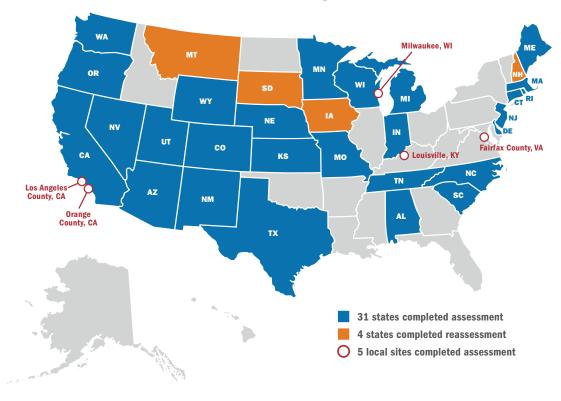
New participants are added each year and our surveys show that they're creating new partnerships and resources such as manuals to contribute to the APHL resource center. This year, labs cited improved communication as a top benefit to participation.



Cliff Cunningham, newborn screening microbiologist 2 at the Tennessee Department of Health, Division of Laboratory Services, instructs a laboratory technician on the correct placement of newborn screening samples in sample plates. Mohamed Adas, newborn screening microbiologist 2 punches newborn screening samples in the background using a Panthera-Puncher.

#### L-SIP PARTICIPATION EXPANDS

Spring 2016



#### The Effects of L-SIP (from the APHL Quality **Improvement Survey):**

- Made contacts within hospital laboratory community for future pilots
- Accepted invitation to state health laboratory's focus group
- Joined state health laboratory's board of external advisors

# **ENVIRONMENTAL HEALTH**



## Creating the National **Biomonitoring Network**

The US lacks a national plan for biomonitoring, the rigorous scientific process that measures levels of potentially harmful chemicals in human tissues and fluids. APHL and our members saw the need for a National Biomonitoring Network. With support from the broader environmental health community, a surveillance network now exists and is being formalized.

Thanks to CDC funding, APHL has developed a network steering committee with representatives from CDC's Division of Laboratory Sciences, CDC's National Institute for Occupational Safety and Health, EPA's National Exposure Laboratory, the National Institute of Environmental Health Sciences and various toxicological, epidemiological and laboratory state agencies.

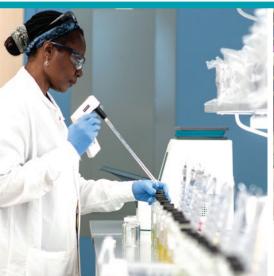
The network's goals dovetail with the priorities of the Agency for Toxic Substances and Disease Registry and the demands of communities who advocated for the Toxic Substances Control Act and use APHL's Biomonitoring Capabilities List to help address their environmental issues.



#### **Cannabis Guidance**

In response to repeated demands from state public health laboratories, our team convened a cannabis community of practice two years ago. Others from across the industry also joined: federal agencies, consultants, growers and scientists. We produced a guidance document based on common questions, gave interviews to Bloomberg Business News, USA Today and other media outlets, and are continuing to address members' ongoing needs.

Left: Lynette Player, Maryland Public Health Laboratory Water Microbiology Unit, analyzing recreational beach water samples for Enterococci. Center: Blood lead collection from elementary school student. Right: Blood lead specimens must dry for at least four hours before being packaged and sent to the laboratory for testing.









College interns observe heterotrophic plate counts from an environmental water sample at the Milwaukee Health Department Laboratory. Pictured left to right: Jean Wojnar (MHDL staff), Raquel Gomez (UW-Milwaukee intern), Abigail Nickrant (Alverno College intern), Sukinah Alhabib (UW-Milwaukee intern) and Michael Mamerow (UW-Milwaukee intern).

# A Growing Connection to EPA

In the past, APHL's relationship with EPA has been mainly about water security. Since APHL acts as a connector—between agencies and within them—our team sought to broaden our connections across EPA and create new paths for partnerships with state public health laboratories. These efforts achieved a draft Memorandum of Understanding with EPA's Office of Research and Development. The document will help APHL members get access to experts and expand opportunities for collaboration.

This widening relationship has already benefited FDA-when APHL connected it to an EPA oil dispersal method—and will aid CDC in current and future projects.

#### **EFFECTIVE LEADERSHIP**



- Convened a webinar on "Biomonitoring—California's Results and Communications"
- Convened a webinar on "Lead Testing, Response and Communications"
- Convened a National **Environmental Health** Index meeting with partners from the National **Environmental Health** Association, Association of State and Territorial Health Directors, EPA and CDC
- In response to a CDC request, determined nationwide public health laboratory testing capability for perflourinated chemicals within three weeks

- Presented "Monitoring and Detecting Health Threats" at the 2nd International Berlin Conference on **Human Biomonitoring**
- Participated in EPA's Office of Children's Health webinar: APHL staff presented on lead poisoning and recruited a Georgetown University professor as a presenter
- Funded the Utah public health laboratory to co-host the Utah Environmental Health Association's biennial regional meetingthe first time a UEHA meeting has included a laboratory component

# CONCLUSION



# Thinking "Outside"

o get good results, I believe we have to get outside: Outside of the laboratory. Outside of the typical ways of thinking. Outside of our comfort zones.

This report shows the results of a year of this kind of reaching beyond. APHL and our members at all levels pushed ourselves. Sometimes it was by necessity, when the tough challenges called for new solutions. Sometimes it was by design—as we developed and expanded new partnerships not only with CDC but also with FDA, EPA, WHO and more.

In Hawaii, where I'm based, we're all advocates of getting outside. It's reflected in every aspect of our lives. We've learned from experience that networking, surveillance, and sharing best laboratory practices among our neighbors and visitors of every state and nation is vital. Because threats—and great ideas—don't stop at the shore of an island.

Working cooperatively is critical to responding to today's crises and preparing for tomorrow's. As an organization, APHL has doubled in size in the past 10 years and is leaping forward due to the quantity and quality of our new connections.

We also brought together 100+ stakeholders from across the public health spectrum to clarify how our field needs to progress. Their willingness to color outside the lines and ignore silos led them to define the six drivers for building a sustainable public health laboratory system. These imperatives form our Vision 2020 and will propel our work:

- Building the connectivity infrastructure so the public health laboratory system can feed into the national surveillance platform
- Explaining the biological and environmental relevance of new technologies to those outside our field
- Ensuring workforce pipelines and capabilities for public health laboratories
- Planning to maintain certain traditional public health laboratory techniques and procedures
- Determining how public health laboratories will engage in a new era of point-of-care diagnostics
- Increasing the engagement of APHL members, especially those who are not active participants

Our collaboration with CDC fueled this vision and makes it possible to achieve it. As new opportunities present themselves, we look forward to expanding connections across CDC.

We'll all be opening doors and getting outside more often. After all, we know that's good for us in every way.

a. Christian When

A. Christian Whelen, PhD, (D)ABMM PRESIDENT, APHL

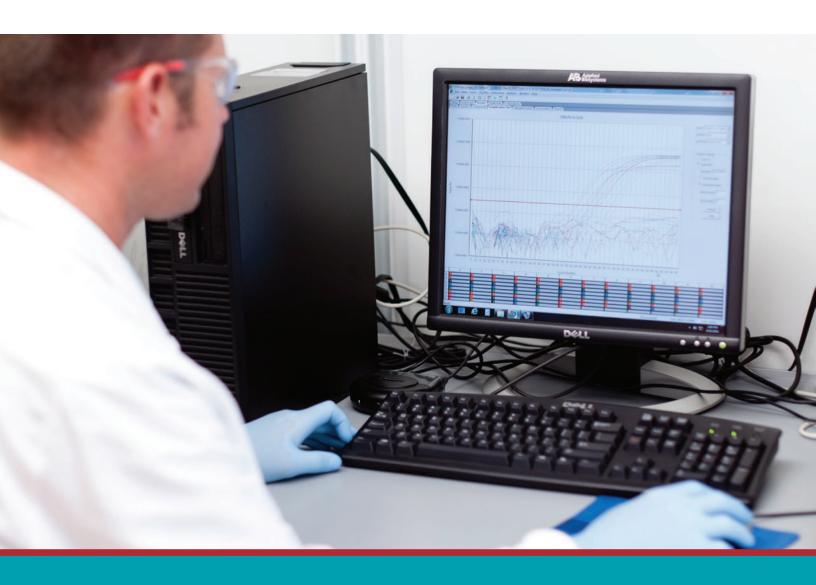


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ABOVE: Analyst Kristen Gilbert of the New York State
Department of Agriculture & Markets Food Laboratory
inspects the torch on the inductively coupled plasma
optical emission spectrometry (ICP-0ES) instrument
before running fertilizer samples. ICP-0ES is an analytical
technique used to detect trace metals.





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